

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

VIVIAN RIVERA-ZAYAS, as Administrator of the
Estate of ANA MARTINEZ, Deceased,

Plaintiff(s),

-against-

OUR LADY OF CONSOLATION GERIATRIC CARE
CENTER, OUR LADY OF CONSOLATION
GERIATRIC CARE CENTER d/b/a OUR LADY OF
CONSOLATION NURSING AND REHABILITATIVE
CARE CENTER, and OUR LADY OF
CONSOLATION NURSING AND REHABILITATIVE
CARE CENTER,

Defendant(s),

**Case No.: 2:20-cv-05153-NGG-
SIL**

**PLAINTIFFS' MEMORANDUM OF LAW OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS THE COMPLAINT PURSUANT
TO FED. R. CIV. P. 12(B)(1) AND 12(B)(6)**

LEITNER VARUGHESE WARYWODA PLLC

Attorneys for Plaintiff

425 Broadhollow Road, Suite 417

Melville, New York 11747

(212) 671-1110

Brett R. Leitner, Esq. (BL 3172)

Justin Varughese, Esq. (JV 9266)

Nicholas E. Warywoda, Esq. (NW 6968)

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
STATEMENT OF FACTS	1
A. Plaintiff’s Allegations	1
B. DOH Charges and Defendants’ Affirmative Admission of Covid-19 Infection Control Violations	3
APPLICABLE LAW	4
I. THE PREP ACT	4
II. THE EDTPA	10
ARGUMENT	12
I. THIS COURT, AND COURTS THROUGHOUT THE UNITED STATES, HAVE DETERMINED THAT THE PREP ACT DOES NOT APPLY TO PLAINTIFF’S CLAIMS	12
II. PLAINTIFF’S CLAIMS DO NOT ARISE OUT OF COVERED COUNTERMEASURES	14
III. PLAINTIFF’S CLAIMS ARE NOT COMPLETELY PREEMPTED AND THEREFORE DO NOT GIVE RISE TO FEDERAL URISDICTION	18
IV. THE EMERGENCY OR DISASTER TREATMENT PROTECTION ACT (EDTPA) WAS REPEALED IN ITS ENTIRETY ON APRIL 6, 2021 AND FAILS TO AFFORD IMMUNITY TO DEFENDANTS HEREIN AGAINST THE INSTANT CLAIMS	21
(A) The Sponsor’s Legislative Intent is of Paramount Consideration	22
(B) Due Process & Public Policy Warrant Retroactive Application of A03397	26

V. THE EDTPA DOES NOT APPLY TO PLAINTIFF’S CLAIMS HEREIN	29
A. Defendants’ Negligence and Violations Occurred Prior to the Pandemic.....	29
B. Defendants’ Actions are Outside the Confines of the EDTPA.....	31
VI. PLAINTIFF PROPERLY ALLEGES CAUSES OF ACTION FOR GROSS NEGLIGENCE AND RECKLESS CONDUCT, AND THE REPEALED IMMUNITY PROVISION EXPLICITLY PERMITS SUCH CLAIMS	33
CONCLUSION.....	35

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Anson v. HCP Prairie Vill. KS OpCo LLC</i> , No. 20-CV-2346 (DDC) (JPO), 2021 WL 308156 (D. Kan. Jan. 29, 2021)	13, 15
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)	33
<i>Aurora Loan Services, LLC v. LaMattina & Associates, Inc.</i> , 59 A.D.3d 578, 872 N.Y.S.2d 724 (2d Dept. 2009)	35
<i>Austin v the Jewish Home</i> , No. 3041962010, 2015 WL 1850183 (N.Y. Sup. Ct. Mar. 20, 2015)	34
<i>Baron v. Incorporated Village of Freeport</i> , 143 A.D.2D 792, 533 N.Y.S.2d 143 (2d Dept 1988)	35
<i>Baskin v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , Case No. 2:20-cv-2267-HLT- JPO, 2020 WL 4815074 (D. Kan. 2020)	12
<i>Becker v. Huss Co.</i> , 43 N.Y.2d 527, 402 N.Y.S.2d 980 (1978)	26
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)	33
<i>Beneficial Nat. Bank v. Anderson</i> , 539 U.S. 1 (2003)	19, 20
<i>Block v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , Case No. 2:20-cv-2262-HLT-JPO, 2020 WL 4815076 (D. Kan. 2020)	12
<i>Brady v. SSC Westchester Operating Company LLC</i> , No. 2-cv-4500 (N.D. Ill. 2021)	32
<i>Bros. v Florence</i> , 95 NY2d 290 [2000]	26
<i>Brown v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , Case No. 2:20-cv-2262-HLT-JPO, 2020 WL 4815078 (D. Kan. 2020)	12, 13, 15

<i>Campbell v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , Case No. 2:20-cv-2265-HLT-JPO, 2020 WL 4815082 (D. Kan. 2020).....	12, 16
<i>CFCU Community Credit Union v. Hayward</i> , 552 F.3d 253 (2009).....	25
<i>City of Oakland v. BP PLC</i> , 969 F.3d 895 (9th Cir. 2020)	18
<i>Coleman v. Eden Park Nursing Homes</i> , No. 0019362/0051, 2007 WL 2236563 (N.Y. Sup. Ct. Albany Co. Apr. 04, 2007)	34
<i>Demicoli v Townhouse Operating Co., LLC</i> , 2009 NY Slip Op 33287(U)(Sup.Ct.Nassau.Co. Index No. 1549/07)	34
<i>Dunn v Schervier Nursing Care Center</i> , No. 147342005, 2013 WL 6702677 (N.Y. Sup. Ct. Bx. Co. June 04, 2013)	34
<i>Dupervil v All. Health Operations, LCC</i> , 2-0CV-4042-, 2021 WL 355137 [EDNY Feb. 2, 2021].....	<i>passim</i>
<i>Eaton v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , Case No. 2:20-cv-2291-HLT-JPO, 2020 WL 4815085 (D. Kan. 2020).....	12, 17
<i>Estate of Jones v. St. Jude Operating Co</i> , Case No. 3:20-cv-01088, 2021 WL 900672 (D. Or. 2021)	12, 17
<i>Estate of Maglioli v. Andover Subacute Rehab. Ctr. I</i> , 478 F. Supp. 3d 518 (D.N.J. 2020)	13, 15
<i>Estate of Smith ex rel. Smith v. The Bristol at Tampa Bay Rehab. & Nursing Ctr.</i> , No. 20-CV-2798 (T) (60SPF), 2021 WL 100376 (M.D. Fla. Jan. 12, 2021)	13, 15
<i>Fortune v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , Case No. 2:20-cv-2318-HLT-JPO, 2020 WL 4815097 (D. Kan. 2020).....	12
<i>Garcia v. New York City Health and Hospitals Corporation</i> , 20-cv9970, 2021 WL 1317178 (SDNY 2021).....	13
<i>Gardner v. Cason, Inc.</i> , 82 A.D.3d 930, 918 N.Y.S.2d 769 (2d Dept 2011)	35
<i>Global Network Commc'ns, Inc. v. City of New York</i> , 458 F.3d 150 (2d Cir. 2006).....	33

<i>Grable & Sons Metal Products, Inc. v. Darue Eng'g & Mfg.</i> , 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005)	9
<i>Gruenfeld v. City of New Rochelle</i> , 72 A.D.3d 1025, 900 N.Y.S.2d 144 (2d Dept. 2010)	35
<i>Gunter v. CCRC OPCO-Freedom Square, LLC</i> , 2020 WL 8461513, 2020 U.S. Dist. LEXIS 201622 (M.D. Fla. Oct. 29, 2020)	13, 15
<i>Hairston v Liberty Behavioral Mgt. Corp.</i> , 2016 NY Slip Op 02724 (138 AD3d 467)(1st Dept. 2016)	34
<i>Hansen</i> , 902 F.3d 1057	18, 19
<i>Harris v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , Case No. 2:20-cv-2266-HLT-JPO, 2020 WL 4815098 (D. Kan. 2020)	12
<i>In re WTC Disaster Site</i> , 414 F.3d 352 (2d Cir. 2005)	20
<i>Isufi v. Prometal Constr., Inc.</i> , 927 F. Supp. 2d 50 (E.D.N.Y. 2013)	20
<i>Jackson v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.</i> , Case No. 2:20-cv-2259-HLT-JPO, 2020 WL 4815099 (D. Kan. 2020)	12, 19
<i>JMD Holding Corp. v. Cong. Fin. Corp.</i> , 828 N.E.2d 604 (2005)	31
<i>Logan v. Zimmerman Brush Co.</i> , 455 U.S. 422, 102 S.Ct. 1148, 71 L.Ed.2d 265 (1982)	27
<i>Long v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , No. 2:20-cv-2263-HLT-JPO, 2020 WL 4815079 (D. Kan. 2020)	12
<i>Lopez v. Life Care Centers of America, Inc.</i> , Case, No. CV 20-0958, 2021 WL 1121034 (D. NM 2021)	12, 16, 18
<i>Lutz v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , Case No. 2:20-cv-02316-HLT-JPO, 2020 WL 4815100 (D. Kan. 2020)	12
<i>Lyons v. Cucumber Holdings, LLC</i> , No. CV-2010571, 2021 WL 364640 (C.D. Cal. Feb. 3, 2021)	17

<i>Majewski v. Broadalbin–Perth Cent. Sch. Dist.</i> , 91 N.Y.2d 577, 673 N.Y.S.2d 966, 696 N.E.2d 978 (1998).....	22, 25, 26, 27
<i>Maltbia v. Big Blue Healthcare</i> , Case No. 20-2607, 2021 WL 1196445 (D. Kan. 2021)	12, 18
<i>Martin v. Serrano Post Acute LLC</i> , No. 20-CV-5937 (DSF) (SK), 2020 WL 5422949 (C.D. Cal. Sept. 10, 2020).....	13, 15
<i>Martinez v. Ashley Apts., Co., LLC</i> , 44 A.D.3d 830, 842 N.Y.S.2d 918 (2d Dept. 2007)	35
<i>Mathews v. Eldridge</i> , 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976).....	27
<i>Matter of Gleason</i> , 96 N.Y.2d 117, 726 N.Y.S.2d 45, 749 N.E.2d 724 (2001).....	26
<i>Matter of Knight–Ridder Broad. v. Greenberg</i> , 70 N.Y.2d 151, 518 N.Y.S.2d 595, 511 N.E.2d 1116 (1987).....	22
<i>Matter of OnBank & Trust Co.</i> , 90 N.Y.2d, 665 N.Y.S.2d 389, 688 N.E.2d 245	26
<i>Meltzer v Pine Grove Manor, II LLC, No.</i> , 2016 WL 510391 (N.Y. Sup. Ct. Queens Co. Feb. 02, 2016)	34
<i>Mueller v Elderwood Health Care at Oakwood</i> , 2011 NY Slip Op 50555(U) (Sup. Ct. Erie. Co Index No. 2008-1416) (April 11, 2011)	34
<i>Osborne v Rivington House</i> , 2008 NY Slip Op 50975(U) [19 Misc 3d 1132(A) (Sup.Ct. NY Co.).....	34
<i>Regina Haro v. Kaiser Foundation Hosps., et al.</i> , Case No. CV 20-6006-GW-JCx, 2020 WL 5291014 (C.D. Cali. 2020)	12
<i>Rivet v. Regions Bank of La.</i> , 522 U.S. 470, 118 S.Ct. 921, 139 L.Ed.2d 912 (1998).....	18
<i>Robertson v. Big Blue Healthcare, Inc.</i> , Case No. 2:20-cv-02561, 2021 WL 764566 (D. Kan. 2021).....	18
<i>Rodina v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.</i> , Case No. 2:20-cv-2319-HLT-JPO, 2020 WL 4815102 (D. Kan. 2020).....	12

<i>Romano v. Kazacos</i> , 609 F.3d 512 (2d Cir. 2010).....	18
<i>Saldana v. Glenhaven Healthcare LLC</i> , No. 20-CV-5631 (FMO) (MAA), 2020 WL 6713995 (C.D. Cal. Oct. 14, 2020)	13, 15
<i>Seidemann v. Professional Staff Congress Local 2334</i> , 432 F.Supp.3d 367 (S.D.N.Y. 2020).....	27
<i>Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC</i> , No. 20-CV-1198, 2020 WL 6140474 (W.D. Pa. Oct. 16, 2020)	13, 15
<i>Smith v. Colonial Care Ctr., Inc. et al.</i> , No. 2:21-CV-00494-RGK-PD, 2021 WL 1087284 (C.D. Cal. Mar. 19, 2021)	16
<i>Stoianoff v. Commissioner of Motor Vehicles</i> , 107 F. Supp. 2d 439 (S.D.N.Y. 2000).....	28
<i>Stone v. Long Beach Healthcare Center, LLC</i> , Case No. 20-2607, 2021 WL 1163572 (D. Kan 2021)	12
<i>Sullivan v. Am. Airlines, Inc.</i> , 424 F.3d 267 (2d Cir. 2005).....	18, 19, 20
<i>Thyme v. City of New York</i> , 22 A.D.3d 571, 801 N.Y.S.2d 744 (2d Dept. 2005)	35
<i>Turner v Northern Manhattan Nursing Home, Inc.</i> , No. 161278/15, 2018 WL 1257003 (N.Y. Sup. Ct. Mar. 12, 2018)	34
<i>United States v. Freight Assn.</i> , 166 U.S. 290, 17 S.Ct. 540 (1897).....	25
<i>United States v. Mead Corp.</i> , 533 U.S. 218, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001).....	19
<i>Vatore v. Comm'r of Consumer Affairs</i> , 83 N.Y.2d 645, 612 N.Y.S.2d 357, 634 N.E.2d 958 (1994).....	22
<i>Vaynberg v Saint Vincents Catholic Medical Centers of New York</i> , No. 37727/06, 2009 WL 3412982 (N.Y. Sup. Ct. Oct. 14, 2009)	34
<i>Warrington v. Ryder Truck Rental, Inc.</i> , 826 N.Y.S.2d 152 (2nd Dept. 2006)	31

Woollcott v. Shubert,
217 N.Y. 212, 111 N.E. 829 [1916].....25

Zinerman v. Burch,
494 U.S. 113, 110 S.Ct. 975, 108 L.Ed.2d 100 (1990).....27

Statutes

21 U.S.C. § 321(h)6

29 U.S.C. § 185.....18

29 U.S.C. § 502(a)18

42 U.S.C. § 247d-6d(a)(1)4, 6, 9, 14, 20

42 U.S.C. § 247d-6d(b)(1)6

42 U.S.C. § 247d-6b(c)(1)(B)6

42 U.S.C. § 247d-6e(d)(1)20

42 U.S.C. § 247d-6d(e)(1)20

42 U.S.C. § 247d-6e(a)19

42 U.S.C. § 247d-6e(b)19

42 U.S.C. § 247d-6d(i)(1)4, 6, 16

42 U.S.C. § 247d-6d(i)(2)8

42 U.S.C. § 247d-6d(i)(7)6, 16

42 U.S.C. §§ 247d-6d(i)(1)(C).....14

42 U.S.C. § 247d-6d(i)(1)(D)14

CPLR § 3212(f).....35

Const. Art. I, § 6.....27

N.Y. Stat. § 54(a) (McKinney 2019)27

Public Health Law § 2801-d27

Public Health Law § 2801-d(2).....34

Public Health Law § 2803(4).....3

Public Health Law § 3080.....10

Pub. Health Law § 3082(1).....31

Pub. Health Law § 3082(2) (McKinney)11

U.S. Const. Amend. V27

Rules

Fed. R. Civ. P. 12(b)(1)

Fed. R. Civ. P. 12(b)(6).....1

Regulations

10 NYCRR § 415.19(a)(1).....3, 15, 30

10 NYCRR § 415.19(a)(2).....3, 15, 30

10 NYCRR § 415.9.....31

42 CFR § 483.80.....30, 31

85 Fed. Reg. 194.....7, 8, 9, 14

85 Fed. Reg. 2026, 7

85 Fed. Reg. 15,198 (Mar. 17, 2020).....4

85 Fed. Reg. 21,012 (Apr. 15, 2020)4

85 Fed. Reg. 35,100 (June 8, 2020)4

85 Fed. Reg. 52,136 (Aug. 24, 2020).....4

85 Fed. Reg. 79,190 (Dec. 9, 2020)4

85 Fed. Reg. 79,194.....19

86 Fed. Reg. 7,872 (Feb. 2, 2021)4

Plaintiff, Vivian Rivera-Zayas, as the Administrator of the Estate of Ana Martinez, respectfully submits this Memorandum of Law in opposition to Defendants' Motion to Dismiss the Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

STATEMENT OF FACTS

This is a New York State nursing home negligence case. Plaintiff's Complaint asserts claims for violations of New York public health code, negligence, gross negligence, and wrongful death, under New York state law, against Defendants herein. All parties hereto are residents of the State of New York. *See* Leitner Decl. Ex. A (Plaintiff's Amended Verified Complaint). The crux of Plaintiff's Complaint is that Defendants' history of infection control violations, lack of infection prevention and control policies, and **failure to act** to prevent entry and/or spread of COVID-19 in their skilled nursing facility, caused the injuries and death of Plaintiff's Decedent, Ana Martinez.

A. Plaintiff's Allegations

Plaintiff's Amended Verified Complaint alleges that Defendants failed to follow policies, protocols, procedures, guidelines, and recommendations to prevent the entry and/or spread of COVID-19 in their nursing home facility. Plaintiff does not plead the failure of a noted countermeasure, i.e. drug, product, or device. Rather, Plaintiff pleads Defendants' failure to act to prevent entry and/or spread of COVID-19 in its facility. The Complaint alleges various state-law claims of negligence, gross negligence, wrongful death, medical and nursing malpractice, and violation of New York Public Health Law. (Id. ¶¶ 57–197.)

Specifically, Plaintiff's Complaint alleges the following, with emphasis added:

Defendants' ... *failure to maintain a system for preventing, identifying, reporting,*

investigating, and controlling infections and communicable diseases, which led to the death of the decedent, ANA MARTINEZ, from COVID-19 ... (Leitner Decl., Ex. A, ¶1).

In 2019, prior to the current coronavirus outbreak, Our Lady of Consolation was cited by government inspectors and regulators multiple times for violations of federal and state regulations for *failing to provide and implement proper infection and control procedures*, and *failing to implement contact isolation precautions* (Leitner Decl., Ex. A, ¶2).

[P]rior to the coronavirus emergency in New York, on February 6, 2020, Our Lady of Consolation was *placed on notice by Centers for Medicare & Medicaid Services that coronavirus infections can rapidly appear and spread, and that it was critical that the nursing home be prepared by planning for infectious disease response*, ... (Leitner Decl., Ex. A, ¶3).

*... failed to take proper precautions to help prevent the development of infections prior to and leading up to the COVID-19 pandemic.*¹

Our Lady of Consolation was issued 31 citations during Certification and Complaint Surveys for violations of public health code between 2016 and 2020 (Leitner Decl., Ex. A, ¶47).

On or about September 12, 2019, Our Lady of Consolation was *cited by the New York State Department of Health* (“DOH”) for federal violations, and violations of its own written policies and procedures, for *failing to order Contact Isolation Precautions* (Leitner Decl., Ex. A, ¶48).

On or about September 12, 2019, Our Lady of Consolation was cited by the DOH for *failing to “ensure that an infection prevention and control program designed to help prevent the development of infections was maintained”* (Leitner Decl., Ex. A, ¶49).

In or about *January 2020*, and likely earlier, *Defendants were made aware of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spreading world-wide and nationally*, known colloquially as the coronavirus, that caused severe medical distress and death in individuals who contracted the disease, especially the elderly. (Leitner Decl., Ex. A, ¶53).

On February 6, 2020, CMS issued written memoranda to Our Lady of Consolation advising that coronavirus infections can rapidly appear and spread, and *facilities must take steps to prepare for this, including reviewing their infection control policies and practices to prevent the spread of infection*. (Leitner Decl., Ex. A, ¶57).

¹ As a direct and foreseeable consequence of the Defendants’ failures, as of June 2, 2020, there was a confirmed COVID-related death count of 39 residents who died inside Our Lady of Consolation due to COVID-19, as well as an unknown, but potentially greater, number of Our Lady of Consolation COVID-19 resident deaths outside of the facility. According to the New York State Department of Health, Our Lady of Consolation claims the highest COVID-related death count of any nursing facility in Suffolk County, and the sixth highest death count in the State of New York. (Leitner Decl., Ex. A, ¶4)

As of February 4, 2021, the number of Our Lady of Consolation confirmed deaths from COVID-19 was 68. According to the New York State Department of Health, Our Lady of Consolation claims the second highest COVID-related death count of any nursing facility in Suffolk County, and one of the highest death counts of any nursing facility in the State of New York.

On or about January 8, 2020 through on or about March 30, 2020, Plaintiff's decedent ANA MARTINEZ was admitted to Defendants' facility, and during her admission, was infected with SARS-CoV-2 and COVID-19, and developed respiratory distress and hypoxia, which resulted in her untimely death on April 1, 2020. (Leitner Decl., Ex. A, ¶60).

[D]uring Plaintiff's decedent ANA MARTINEZ's stay at [Defendants'] nursing home, she was infected with SARS-CoV-2 and contracted COVID-19, and suffered respiratory distress, hypoxia, and other injuries, caused by the negligence of [Defendant] and violation of [Defendants'] contract with Plaintiff's decedent ANA MARTINEZ, laws, rules, statutes and ordinances without any negligence on the part of the Plaintiff's decedent ANA MARTINEZ, which caused her death. (Leitner Decl., Ex. A, ¶88-90).

B. DOH Charges and Defendants' Affirmative Admission of Covid-19 Infection Control Violations.

On May 11, 2020, a New York State Department of Health ("DOH") investigation uncovered various failures and violations committed by Defendants in response to the COVID-19 pandemic. Pursuant to the DOH findings, Defendants **explicitly admitted** to multiple infection control failures and violations of Public Health Law Section 2803(4), 10 NYCRR 415.19(a)(1), 415.19(a)(2) and Governor's Executive Orders 202.18 and 202.19. As a result of the violations, Defendants entered into a Stipulation and Order admitting fault, and were consequently fined \$10,000.00. (See DOH Stipulation and Order, Leitner Decl., Ex. B).

Specifically, the Stipulation and Order reveals that Defendants admitted to violations found during the May 11, 2020 Survey of 10 NYCRR 415.19, of:

- 1) *failing to establish an infection control program with written policies and procedures under which it investigates, controls and takes action to prevent infections in the facility (10 NYCRR 415.19(a)(1));*
- 2) *failing to establish an infection control program with written policies and procedures under which it determines what procedures such as isolation and universal precautions should be utilized for an individual resident and implements the appropriate procedures (10 NYCRR 415.19(a)(2)); and*

- 3) failing to notify family members or next of kin if any resident tests positive for COVID-19, or if any resident suffers a COVID-19 related death, within 24 hours of such positive test result or death. (Executive Order 202.18).

APPLICABLE LAW

I. THE PREP ACT

Most recently, the Hon. Justice Pamela K. Chen of this Court held that the Court lacked subject matter jurisdiction as the PREP Act was not applicable to plaintiff's claims in *Dupervil v All. Health Operations, LCC*, 2-0CV-4042-, 2021 WL 355137 [EDNY Feb. 2, 2021], an almost identical nursing home negligence matter relating to COVID-19 failures as herein. In *Dupervil*, Justice Chen detailed the history of the PREP Act as follows:

The PREP Act generally provides that

a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration [by the Secretary of Health and Human Services] has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(a)(1). In March 2020, the Secretary of Health and Human Services ("the Secretary") issued a declaration under the PREP Act regarding the COVID-19 pandemic. 85 Fed. Reg. 15,198 (Mar. 17, 2020). The Declaration has since been amended five times.²

A "covered countermeasure" under the PREP Act is defined as "a qualified pandemic or epidemic product"; "a security countermeasure"; a "drug ..., biological product ..., or device ... that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [*i.e.*, FDCA]"; or "a respiratory protective device that is approved by the National Institute for Occupational Safety and Health [*i.e.*, NIOSH], ... and that the Secretary determines to be a priority for use during a public health emergency declared under section 247d of this title." 42 U.S.C. § 247d-6d(i)(1). The statute in turn defines both a "qualified pandemic or epidemic product" and a "security countermeasure." A qualified pandemic or epidemic product is

² See First Amended Declaration, 85 Fed. Reg. 21,012 (Apr. 15, 2020); Second Amended Declaration, 85 Fed. Reg. 35,100 (June 8, 2020); Third Amended Declaration, 85 Fed. Reg. 52,136 (Aug. 24, 2020); Fourth Amended Declaration, 85 Fed. Reg. 79,190 (Dec. 9, 2020); Fifth Amended Declaration, 86 Fed. Reg. 7,872 (Feb. 2, 2021).

a “drug,” “biological product,” or “device” that is

- (i) a product manufactured, used, designed, developed, modified, licensed, or procured (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or (II) to limit the harm such pandemic or epidemic might otherwise cause;
- (ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or
- (iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii)[.]

Id. § 247d-6d(i)(7)(A). Such drug, biological product, or device must also be approved or cleared under the FDCA, licensed under the Public Health Service Act (“PHSA”), subject to an exemption, or authorized for emergency use. *Id.* § 247d-6d(i)(7)(B).

A security countermeasure is a “drug,” “biological product,” or “device” that

- (i)(I) the Secretary determines to be a priority ... to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat [by the Secretary of Homeland Security], or to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; (II) the Secretary determines ... to be a necessary countermeasure; and (III) (aa) is approved or cleared under [the FDCA] or licensed under [the PHSA]; or (bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination [that procurement of the countermeasure is appropriate]; or
- *3 (ii) is authorized for emergency use under section 564 of the [FDCA].³

A “biological product” is “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of

³ *Id.* § 247d-6b(c)(1)(B); see also *id.* § 247d-6d(i)(1)(B).

human beings.” *Id.* § 262(i); *see also id.* §§ 247d-6b(c)(1)(B), 247d-6d(i)(7). The term “device,” which is adopted from the FDCA, means “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory” that is

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.⁴

In accordance with the various terms of the PREP Act, the Secretary’s March 2020 Declaration under the Act specifically defines a “covered countermeasure” as

any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.⁵

Id. at 79,196. Yet, the Secretary has consistently made clear that “[t]o be a Covered Countermeasure under the Declaration, a product must also meet [the] definition of ‘Covered Countermeasure’ ” as set forth in 42 U.S.C. § 247d-6d(i)(1), discussed above. *Id.*; *see also* Declaration, 85 Fed. Reg. at 15,202; First Amended Declaration, 85 Fed. Reg. at 21,014; Second Amended Declaration, 85 Fed. Reg. at 35,102.

Given that liability immunity under the PREP Act applies only to claims for loss “caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure,” 42 U.S.C. § 247d-6d(a)(1), the meaning of the term “administration” is also important. “The PREP Act does not explicitly define the term ‘administration’ but does assign the Secretary the responsibility to provide relevant conditions in the Declaration.” Declaration, 85 Fed. Reg. at 15,200; *see also* 42 U.S.C. § 247d-6d(b)(1). The Secretary’s March 2020 Declaration accordingly provides that “administration” of covered countermeasures “means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients,

⁴ 21 U.S.C. § 321(h); *see also* 42 U.S.C. §§ 247d-6b(c)(1)(B), 247d-6d(i)(7).

⁵ Declaration, 85 Fed. Reg. at 15,202. This definition, however, has been expanded several times since March 2020. *See Dupervil v All. Health Operations, LCC*, 2-0CV-4042-, 2021 WL 355137 [EDNY Feb. 2, 2021].

management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.” Declaration, 85 Fed. Reg. at 15,202. The Declaration further explains in the preamble:

The definition of “administration” extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act. Under the definition, these liability claims are precluded if they allege an injury caused by a countermeasure, or if the claims are due to manufacture, delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary’s interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure’s administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

In December 2020, the Secretary amended the Declaration “to make explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act” and the liability protections it affords. Fourth Amended Declaration, 85 Fed. Reg. at 79,194. Accordingly, “[w]here there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute ‘relating to ... the administration to ... an individual’ under [the PREP Act].” *Id.* at 79,197. In other words, “[p]rioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP

Act” and its liability protections. *Id.* The Fourth Amended Declaration specifically contemplates a situation where there is a limited number of COVID-19 vaccines and a covered person under the Act chooses not to administer vaccines to those in less vulnerable populations so that those in more vulnerable populations may be vaccinated. *See id.*

A “covered person” under the Act includes:

- (A) the United States; or (B) a person or entity that is (i) a manufacturer of [a covered] countermeasure; (ii) a distributor of such countermeasure; (iii) a program planner of such countermeasure; (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or (v) an official, agent, or employee of a person or entity described in clauses (i), (ii), (iii), or (iv).

42 U.S.C. § 247d-6d(i)(2). The term “person” is defined broadly and “includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.” *Id.* § 247d-6d(i)(5). Additionally, the term “program planner” means

a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration [issued by the Secretary].

Id. § 247d-6d(i)(6). Neither the text of the statute nor the Secretary’s Declaration expressly includes nursing homes within the definition of “covered person.”⁶ (Advisory Opinion 20-04, Dkt. 16, at 3.) Moreover, HHS’s Office of the General Counsel has issued at least one opinion letter in response to a specific inquiry that concludes that “senior living communities are ‘covered persons’ under the PREP Act when they provide a facility to administer or use a covered countermeasure in accordance with the Secretary’s March 10, 2020 Declaration under the PREP Act.” (Letter from Robert P. Charrow,

⁶ However, the Fourth Amended Declaration makes clear that it “must be construed in accordance with the Advisory Opinions of the Office of the General Counsel [of Health and Human Services (“HHS”)] (Advisory Opinions),” and the Declaration expressly incorporates such Advisory Opinions. Fourth Amended Declaration, 85 Fed. Reg. at 79,194–95. One of these Advisory Opinions provides that

any individual or organization can potentially be a program planner and receive PREP Act coverage. So for example, private businesses, public and private transportation providers, public and private schools, and religious organizations are all eligible for PREP Act coverage when they act in accordance with the PREP Act and the Declaration.

General Counsel, HHS, to Thomas Baker, Foley Hoag LLP (Aug. 14, 2020), Dkt. 13-9, at 1.) Yet, this opinion letter plainly states: “[This letter] is not a final agency action or a final order. Nor does it bind HHS or the federal courts. It does not have the force or effect of law.” (*Id.* at 2.)

When the PREP Act applies, it provides broad immunity “from suit and liability under Federal and State law,” 42 U.S.C. § 247d-6d(a)(1), and the remedy available to an injured plaintiff is an administrative “Covered Countermeasure Process Fund” (“Process Fund”), administered by the Secretary, that provides “timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure,” *see id.* §§ 247d-6e(a), 247d-6e(b)(1). “No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary” in administering the Process Fund, *id.* § 247d-6e(b)(5)(C), and compensation through the Process Fund “shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses,” *id.* § 247d-6e(d)(4).⁷

The PREP Act also includes a provision expressly preempting state laws that conflict with the terms of the Act:

During the effective period of a declaration [by the Secretary], or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the [FDCA].⁸ ...

⁷ The only exception is if there is “death or serious physical injury proximately caused by willful misconduct,” *id.* § 247d-6d(d)(1), in which case an action may “be filed and maintained only in the United States District Court for the District of Columbia,” *id.* § 247d-6d(e)(1). Even so, there is an administrative exhaustion requirement before a plaintiff may bring a suit for injury proximately caused by willful misconduct, *id.* § 247d-6e(d)(1), and the plaintiff may instead elect to accept compensation from the Process Fund, if the Secretary determines that the plaintiff qualifies, *id.* § 247d-6e(d)(5).

⁸ *Id.* § 247d-6d(b)(8). Furthermore, the Secretary’s Fourth Amended Declaration states that “there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005), in having a uniform interpretation of the PREP Act.” Fourth Amended Declaration, 85 Fed. Reg. at 79,197. Even more recently,

(See *Dupervil v All. Health Operations, LCC*, 20-CV-4042, 2021 WL 355137 (EDNY Feb. 2, 2021), Leitner Decl., Ex. D).

II. THE EDTPA

On April 6, 2020, the Emergency or Disaster Treatment Protection Act, Public Health Law Article 30-D (since repealed) was enacted, codified under N.Y. Pub. Health Law § 3080. The Act provided for limited immunity for COVID-19-related treatment if specific conditions were met:

any health care facility or health care professional shall have immunity from any liability, civil or criminal, for any harm or damages alleged to have been sustained as a result of an act or omission in the course of arranging for or providing health care services, if:

- (a) the health care facility or health care professional is arranging for or providing health care services pursuant to a COVID–19 emergency rule or otherwise in accordance with applicable law;
- (b) the act or omission occurs in the course of arranging for or providing health care services and the treatment of the individual is impacted by the health care facility's or health care professional's decisions or activities in response to or as a result of the COVID–19 outbreak and in support of the state's directives; **and**
- (c) the health care facility or health care professional is arranging for or providing health care services in good faith.

In addition to these requirements, the statute provided that immunity **does not apply** if:

the harm or damages were caused by an act or omission constituting willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm by the health care facility or health care professional providing health care services, provided, however, that acts, omissions or decisions resulting from a resource or staffing shortage shall not be considered to be willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm.

HHS's Office of the General Counsel issued another Advisory Opinion opining that the PREP Act "is a 'complete preemption' statute" and that the Secretary's determination that the Act implicates a "substantial" federal question "provides the underlying basis for invoking the Grable doctrine." (See Advisory Opinion 21-01, Dkt. 17-1.)

N.Y. Pub. Health Law § 3082(2) (McKinney) (emphasis added).

Soon after the issuance of the immunity enactment, the New York Attorney General investigated the failures of New York nursing homes in response to the COVID-19 pandemic and issued a scathing report finding, *inter alia*, that New York nursing homes vastly undercounted the number of COVID-related deaths by as much as 50 percent, and that nursing homes' lack of compliance with infection control protocols put residents at increased risk of harm, including:

- Failing to properly isolate residents who tested positive for COVID-19;
- Failing to adequately screen or test employees for COVID-19;
- Demanding that sick employees continue to work and care for residents or face retaliation or termination;
- Failing to train employees in infection control protocols; and
- Failing to obtain, fit, and train caregivers with PPE.

(See Attorney General Investigation, Leitner Decl., Ex. C). The Attorney General specifically concluded that

“To the extent that the executive order and/or EDTPA were interpreted by any nursing homes as providing blanket immunity for harm to residents other than intentional harm, even if the harm was related to intentional resource and staffing allocations, Attorney General James disagrees with such an interpretation as illogical, contrary to public policy, and contrary to the law’s intent.”

(See Attorney General Investigation, Leitner Decl., Ex. C, p. 38).

The previously unknown findings contained in the Attorney General’s report led to public outcry for full repeal of the EDPTA. On April 6, 2021, the Emergency or Disaster Treatment Protection Act (EDTPA) under Article 30-D of the Public Health Law was **repealed in its entirety**.

As set forth in the Affidavit of New York State Assembly Member, Ronald T. Kim, the Sponsor of the Bill to repeal the EDTPA (Assembly Bill A03397), the repeal was intended to apply **retroactively as of March 7, 2020**, “so as to afford victims of nursing home negligence their day

in Court should they so choose, and seek justice pursuant to the available causes of action under state law which provide civil remedies to protect nursing home residents.” (See Affidavit of Assemblyman Kim, Leitner Decl., Ex. E).

ARGUMENT

I. THIS COURT, AND COURTS THROUGHOUT THE UNITED STATES, HAVE DETERMINED THAT THE PREP ACT DOES NOT APPLY TO PLAINTIFF’S CLAIMS.

At the outset, Defendants neglect to advise the Court of the myriad recent federal court decisions finding that the PREP Act’s provisions regarding the administration or use of covered countermeasures do not apply to nursing home negligence allegations concerning failure to follow policies, procedures, and guidelines regarding COVID-19.⁹

Most recently, the Hon. Justice Pamela K. Chen of this Court issued a very comprehensive Order in *Dupervil v All. Health Operations, LCC*, 20-CV-4042, 2021 WL 355137 (EDNY Feb. 2, 2021), an almost identical nursing home negligence matter, finding that the Court lacks subject matter jurisdiction as the PREP Act was not applicable, and that “[t]his Court, like the District of

⁹ See, *Estate of Jones v. St. Jude Operating Co*, Case No. 3:20-cv-01088, 2021 WL 900672 (D. Or. 2021); *Lopez v. Life Care Centers of America, Inc.*, Case No. CV 20-0958, 2021 WL 1121034 (D. NM 2021); *Maltbia v. Big Blue Healthcare*, Case No. 20-2607, 2021 WL 1196445 (D. Kan. 2021); *Stone v. Long Beach Healthcare Center, LLC*, Case No. 20-2607, 2021 WL 1163572 (D. Kan. 2021); *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, Case Nos. 20-665, 20-69852020 WL 4671091 (D. N.J. 2020); see also *Regina Haro v. Kaiser Foundation Hosps., et al.*, Case No. CV 20-6006-GW-JCx, 2020 WL 5291014 (C.D. Cali. 2020); *Baskin v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-2267-HLT-JPO, 2020 WL 4815074 (D. Kan. 2020); *Block v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-2262-HLT-JPO, 2020 WL 4815076 (D. Kan. 2020); *Brown v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-2261-HLT-JPO, 2020 WL 4815078 (D. Kan. 2020); *Campbell v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-2265-HLT-JPO, 2020 WL 4815082 (D. Kan. 2020); *Eaton v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-2291-HLT-JPO, 2020 WL 4815085 (D. Kan. 2020); *Fortune v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-2318-HLT-JPO, 2020 WL 4815097 (D. Kan. 2020); *Harris v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-2266-HLT-JPO, 2020 WL 4815098 (D. Kan. 2020); *Jackson v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehabilitation, et al.*, Case No. 2:20-cv-2259-HLT-JPO, 2020 WL 4815099 (D. Kan. 2020); *Long v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, No. 2:20-cv-2263-HLT-JPO, 2020 WL 4815079 (D. Kan. 2020); *Lutz v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-02316-HLT-JPO, 2020 WL 4815100 (D. Kan. 2020); *Rodina v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-2319-HLT-JPO, 2020 WL 4815102 (D. Kan. 2020).

New Jersey and every other federal court to have examined the issue, agrees that the federal-officer statute cannot be read as broadly as Defendants would like it to be”, and “Defendants do not otherwise qualify for federal-officer removal”. (See *Dupervil v All. Health Operations, LCC*, 20CV-4042-, 2021 WL 355137 [EDNY Feb. 2, 2021], Leitner Decl., Ex. D). In so finding, Justice Chen stated as follows:

The Court is far from alone in reaching this conclusion. In fact, there is a growing consensus among courts across the country that state-law claims of negligence and wrongful death brought against a nursing home for failure to protect against the spread of COVID-19, like those that Plaintiff alleges, are not properly characterized as federal-law claims under the PREP Act.¹⁰

The Court agrees with the consensus among district courts across the country that state-law claims of negligence and wrongful death like those Plaintiff alleges here are not federal-law claims under the PREP Act.

Similarly, just last week, the Southern District of New York (McMahon, C.J.) addressed this issue in *Garcia v. New York City Health and Hospitals Corporation*, 20-cv9970, 2021 WL 1317178 (SDNY 2021), likewise finding that the PREP Act was not applicable:

“Merely complying with federal directives does not fall within the scope of Section 1442(a)(1), even if the actor is a highly regulated private entity that is following federal regulations (as every hospital must in the care of patients, pandemic or not). (citations omitted). As Judge Chen held in *Dupervil*, “there must exist a ‘special relationship’ between” the federal and private entities, something that is utterly lacking here. Long before there was any pandemic, the

¹⁰ In so holding, the *Dupervil* Court cited to the following decisions: *Anson v. HCP Prairie Vill. KS OpCo LLC*, No. 20-CV-2346 (DDC) (JPO), 2021 WL 308156, at 9–11 (D. Kan. Jan. 29, 2021); *Estate of Smith ex rel. Smith v. The Bristol at Tampa Bay Rehab. & Nursing Ctr.*, No. 20-CV-2798 (T) (60SPF), 2021 WL 100376, at *1–2 (M.D. Fla. Jan. 12, 2021); *Gunter v. CCRC OPCO-Freedom Square, LLC*, No. 20-CV-1546, 2020 WL 8461513, at *———, 2020 U.S. Dist. LEXIS 201622, at *9–15 (M.D. Fla. Oct. 29, 2020); *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, No. 20-CV-1198, 2020 WL 6140474, at *7–8 (W.D. Pa. Oct. 16, 2020); *Saldana v. Glenhaven Healthcare LLC*, No. 20-CV-5631 (FMO) (MAA), 2020 WL 6713995, at *2 (C.D. Cal. Oct. 14, 2020); *Martin v. Serrano Post Acute LLC*, No. 20-CV-5937 (DSF) (SK), 2020 WL 5422949, at *2 (C.D. Cal. Sept. 10, 2020); *Brown v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1196, ——— (D. Kan. 2020); *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 525–34 (D.N.J. 2020).

Second Circuit ruled that a health center is not acting under a federal officer simply because it receives federal funding and is subject to “a host of federal requirements and regulations pertaining to the health services it provides.”

II. PLAINTIFF’S CLAIMS DO NOT ARISE OUT OF COVERED COUNTERMEASURES.

As the Court in *Dupervil* stated:

By its plain terms, the PREP Act applies to “all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1). The statute in turn, along with the Secretary’s Declaration, provides that a “covered countermeasure” encompasses any “qualified pandemic or epidemic product,” which is a “drug,” “biological product,” or “device” that meets specified criteria and regulatory standards. *See id.* §§ 247d-6d(i)(1), 247d-6d(i)(7); Fourth Amended Declaration, 85 Fed. Reg. at 79,193. Covered countermeasures also include “respiratory protective device[s]” approved by NIOSH, as well as drugs, biological products, or devices authorized for emergency use under the FDCA. *See* 42 U.S.C. §§ 247d-6d(i)(1)(C)–(D); First Amended Declaration, 85 Fed. Reg. at 21,013–14.

None of Plaintiff’s claims herein alleges loss “caused by, arising out of, relating to, or resulting from the administration to ... an individual” of such covered countermeasures, even accepting the Secretary’s recent interpretation that “administration to” an individual can include “[p]rioritization or purposeful allocation” of a covered countermeasure. *See* Fourth Amended Declaration, 85 Fed. Reg. at 79,197. Rather, the crux of Plaintiff’s claims is that Ana Martinez died because Defendants failed to:

maintain a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals, failed to implement contact isolation precautions, failed to be prepared by planning for infectious disease response, failed to ensure an appropriate care plan documented regarding contact precautions, failed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infections, failed to investigate,

control and take action to prevent infections in the facility; failed to determine what procedures such as isolation and universal precautions should be utilized, failed to contact and advise family members when their loved ones contracted coronavirus, failed to permit family members to contact residents or even see them before they died, failed to take steps to prepare to prevent the spread of future infections. (See Leitner Decl., Ex. A, ¶¶1, 2, 3, 48, 49, 51, 59, 61).

In fact, **Defendants admitted to such violations** including

- 1) *failing to establish an infection control program with written policies and procedures under which it investigates, controls and takes action to prevent infections in the facility* (10 NYCRR 415.19(a)(1));
- 2) *failing to establish an infection control program with written policies and procedures under which it determines what procedures such as isolation and universal precautions should be utilized for an individual resident and implements the appropriate procedures* (10 NYCRR 415.19(a)(2)); and
- 3) *failing to notify family members or next of kin if any resident tests positive for COVID-19, or if any resident suffers a COVID-19 related death, within 24 hours of such positive test result or death.* (Executive Order 202.18). (See Stipulation and Order, Leitner Decl., Ex. C).

These alleged failures cannot be said to be from administering—or even prioritizing or purposefully allocating—a drug, biological product, or device to an individual within the meaning of the PREP Act such that Plaintiffs’ claims are completely preempted.¹¹

Defendants herein argue that Plaintiff’s injuries are related to the use of covered

¹¹ See, *Dupervil v All. Health Operations, LCC*, 2-0CV-4042-, 2021 WL 355137 [EDNY Feb. 2, 2021]; *Anson v. HCP Prairie Vill. KS OpCo LLC*, No. 20-CV-2346 (DDC) (JPO), 2021 WL 308156, at 9–11 (D. Kan. Jan. 29, 2021); *Estate of Smith ex rel. Smith v. The Bristol at Tampa Bay Rehab. & Nursing Ctr.*, No. 20-CV-2798 (T) (60SPF), 2021 WL 100376, at *1–2 (M.D. Fla. Jan. 12, 2021); *Gunter v. CCRC OPCO-Freedom Square, LLC*, No. 20-CV-1546, 2020 WL 8461513, at *———, 2020 U.S. Dist. LEXIS 201622, at *9–15 (M.D. Fla. Oct. 29, 2020); *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, No. 20-CV-1198, 2020 WL 6140474, at *7–8 (W.D. Pa. Oct. 16, 2020); *Saldana v. Glenhaven Healthcare LLC*, No. 20-CV-5631 (FMO) (MAA), 2020 WL 6713995, at *2 (C.D. Cal. Oct. 14, 2020); *Martin v. Serrano Post Acute LLC*, No. 20-CV-5937 (DSF) (SK), 2020 WL 5422949, at *2 (C.D. Cal. Sept. 10, 2020); *Brown v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1196, ——— (D. Kan. 2020); *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 525–34 (D.N.J. 2020).

countermeasures, because Defendants purportedly used some personal protective equipment (“PPE”) and treated Ms. Martinez with FDA-approved medications and devices such as Tylenol and a thermometer. However, as established, the crux of Plaintiff’s claims involves longstanding infection control failures, and inaction, or failure to act, which do not involve administering, or even purposefully allocating, “covered countermeasures,” which the plain terms of the PREP Act define as certain drugs, biological products, and devices. See 42 U.S.C. §§ 247d-6d(i)(1), 247d-6d(i)(7); see, *Dupervil v All. Health Operations, LCC*, 2-0CV-4042-, 2021 WL 355137 [EDNY Feb. 2, 2021].

To be sure, the Complaint certainly does not allege that COVID-19 testing or the use of PPE equipment injured anyone. Defendants twist and misconstrue Plaintiff’s allegations in an attempt to shoehorn same within the strict boundaries of the PREP Act. “To the extent Defendants want to argue that the PREP Act applies, they must do so based on the complaint as it is—not as Defendants would prefer it to be.” *Campbell v. Big Blue Healthcare, Inc. d/b/a Riverbend Post-Acute Rehab., et al.*, Case No. 2:20-cv-2265-HLT-JPO, 2020 WL 4815082, at *7 (D. Kan. 2020).

Several other courts have applied similar reasoning and concluded that the PREP Act does not apply to inaction claims unless they allege some causal connection between plaintiff’s injuries and the administration of a covered countermeasure. See *Lopez v. Life Care Ctrs. of Am., Inc.*, No. CV 20-0958 JCH/LF, 2021 WL 1121034, at *8 (D.N.M. Mar. 24, 2021) (PREP Act did not apply to plaintiffs’ claims because it “requires connection to the use or administration of a covered countermeasure” and plaintiffs’ did not allege their injuries resulted from “the implementation of a CDC-approved prioritization plan”); *Smith v. Colonial Care Ctr., Inc. et al.*, No. 2:21-CV-00494-RGK-PD, 2021 WL 1087284, at *4 (C.D. Cal. Mar. 19, 2021) (plaintiff’s claims did not fall within PREP Act because plaintiffs did “not allege any injury related to the use (or non-use) or

administration of any drug, device, or product" and plaintiff's did allege "Decedent's injuries were caused by Defendant's failure to 'implement an effective policy for isolating proven or suspected carriers of the coronavirus, and protecting its residents from exposure to COVID-19.'"); *Lyons v. Cucumber Holdings, LLC*, No. CV-2010571, *19 2021 WL 364640, at *5 (C.D. Cal. Feb. 3, 2021) (citing *Eaton*, 480 F. Supp. 3d at 1194) (finding PREP Act inapplicable because "even assuming that Plaintiff's allegations could be construed as alleging the administration of covered countermeasures, she does not allege that Decedent's death resulted from Defendants' decisions to administer those covered countermeasures to other individuals");

Defendants grasp at straws in relying on a single recent "tentative" decision by a court in the District Court for the Central District of California, which found the Advisory Opinion persuasive and, relying on the Advisory Opinion, concluded that the PREP Act is a complete preemption statute. *See Garcia v. Welltower OpCo Grp.*, No. 20-CV-2250 (JVS) (KES)). This Court addressed *Garcia* in the *Dupervil* opinion finding that this Court "respectfully disagrees and concludes that the Advisory Opinion is unpersuasive and not entitled to any deference". Herein, unlike *Garcia*, where the court found that plaintiff did not allege "instances of nonfeasance . . . but rather instances where [defendants] acted in ways to 'limit the harm such a pandemic or epidemic might otherwise cause'", Plaintiff does not allege any facts asserting that Defendants tried to limit the spread of COVID-19 or implemented any covered countermeasures. Plaintiff herein alleges the exact opposite – that Defendants entirely failed to act, and failed to implement proper infection control.

District courts throughout the United States have likewise found *Garcia* as an "outlier", "not persuasive", and "against the weight of authority" holding that complete preemption does not apply to nursing home negligence cases alleging a failure to act. *See, e.g., Estate of Jones through*

Brown v. St. Jude Operating Company, LLC, Case No. 2:20-cv-02561, 2021 WL 900672 (D. Ore. 2021); *Robertson v. Big Blue Healthcare, Inc.*, Case No. 2:20-cv-02561, 2021 WL 764566 (D. Kan. 2021); *Maltbia v. Big Blue Healthcare*, Case No. 20-2607, 2021 WL 1196445 (D. Kan. 2021); *Lopez v. Life Care Ctrs. of Am., Inc.*, No. CV 20-0958, 2021 WL 1121034, at *8 (D.N.M. 2021).

III. PLAINTIFF’S CLAIMS ARE NOT COMPLETELY PREEMPTED AND THEREFORE DO NOT GIVE RISE TO FEDERAL JURISDICTION.

As summarized by this Court in *Dupervil*,

[T]he well-pleaded complaint rule prohibits parties from manufacturing federal jurisdiction by way of a federal affirmative defense. The “corollary” to this rule is that “a plaintiff may not defeat federal subject-matter jurisdiction by ‘artfully pleading’ his complaint as if it arises under state law where the plaintiff’s suit is, in essence, based on federal law.” *Sullivan v. Am. Airlines, Inc.*, 424 F.3d 267, 271 (2d Cir. 2005) (citing, *inter alia*, *Rivet v. Regions Bank of La.*, 522 U.S. 470, 475–76, 118 S.Ct. 921, 139 L.Ed.2d 912 (1998)). “The artful pleading rule applies when Congress has either (1) so completely preempted, or entirely substituted, a federal law cause of action for a state one that plaintiff cannot avoid removal by declining to plead necessary federal questions, or (2) expressly provided for the removal of particular actions asserting state law claims in state court.” *Romano v. Kazacos*, 609 F.3d 512, 519 (2d Cir. 2010)

Complete preemption is extremely “rare.” *Hansen*, 902 F.3d at 1057. The Supreme Court has found complete preemption applicable to only three federal statutes. See *City of Oakland v. BP PLC*, 969 F.3d 895, 905 (9th Cir. 2020) (noting that complete preemption applies only to § 301 of the Labor Management Relations Act, 29 U.S.C. § 185, § 502(a) of the Employee Retirement Income Security Act of 1974, and §§ 85 and 86 of the National Bank Act). While discussing the limited nature of the doctrine, the Ninth Circuit held that “complete preemption for purposes of federal jurisdiction under Section 1331 exists when Congress: (1) intended to displace a state-law cause of action, and (2) provided a substitute cause of action.” *City of Oakland*, 969 F.3d at 906

(citing *Hansen*, 902 F.3d at 1057). Thus, before complete preemption can apply to a plaintiff's state law claims, the "the claims at issue must fall within the scope of the relevant federal statute." *Jackson v. Big Blue Healthcare, Inc.*, 2020 WL 4815099, at *3–4 (D. Kan. Aug. 19, 2020) (citing *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 9 n.5 (2003)).

This Court in *Dupervil* provided a meticulous analysis in determining that the PREP Act does not completely preempt state-law claims within its scope such that those claims are really federal-law claims, summarized in part below:

Here, the PREP Act does not provide the exclusive cause of action for claims that fall within its scope; in fact, for the most part, the Act provides no causes of action at all.

... in providing immunity from suit to certain covered persons for certain types of claims, the PREP Act confers primary jurisdiction over most claims within its scope not to the federal courts but to the Secretary, who has the sole authority to administer and provide compensation from a "Covered Countermeasure Process Fund." *See* 42 U.S.C. §§ 247d-6e(a), 247d-6e(b). ... Thus, except for one narrow exception, PREP Act claims cannot be brought in federal court. ... Accordingly, just as the Second Circuit in *Sullivan* concluded that the RLA does not completely preempt state-law claims that come within its scope, so too does this Court conclude that the PREP Act does not completely preempt state-law claims within its scope. *See id.* at 276–77.

Defendants also point to a recent January 8, 2021 Advisory Opinion by HHS's Office of the General Counsel, which opines that the PREP Act "is a 'complete preemption' statute" because it establishes "a federal cause of action, *administrative or judicial*, as the only viable claim." (Advisory Opinion 21-01, Dkt. 17-1, at 2 (emphasis added).) In other words, according to the Advisory Opinion, a statute provides an exclusive federal cause of action for purposes of complete preemption even if "the exclusive initial venue is a federal administrative agency." (*See id.*) Although the Secretary's Declaration under the PREP Act "must be construed in accordance with the Advisory Opinions of the Office of the General Counsel," Fourth Amended Declaration, 85 Fed. Reg. 79,194–95, the Advisory Opinion here expressly states that it "does not have the force or effect of law" (Advisory Opinion 21-01, Dkt. 17-1, at 5). Thus, even assuming that Congress intended to delegate authority to the Secretary and HHS's Office of the General Counsel "generally to make rules carrying the force of law," the Office of the General Counsel interpretation relied upon by Defendants here explicitly was not "promulgated in the exercise of that authority" and is not entitled to *Chevron* deference. *See United States v. Mead Corp.*, 533 U.S. 218, 226–27, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001)

... The Advisory Opinion cites no cases for its proposition that an exclusive federal administrative remedy is sufficient for complete preemption. (*See* Advisory Opinion 21-

01, Dkt. 17-1, at 2.) And in fact, the Second Circuit has indicated just the opposite. ... *see also Isufi v. Prometal Constr., Inc.*, 927 F. Supp. 2d 50, 58 (E.D.N.Y. 2013) (“It would be ‘internally inconsistent’ to assert that a district court has jurisdiction for the purpose of removal but that the court must then dismiss the action because the statute confers primary jurisdiction on another adjudicative body.” (citing *Sullivan*, 424 F.3d at 276–77)).²

Finally, Defendants point to a recent filing by the United States Attorney’s Office for the Middle District of Tennessee in a similar case to this one, also involving a nursing home. (Dkt. 18 (attaching Statement of Interest of the United States, *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, No. 20-CV-683 (M.D. Tenn. Jan. 19, 2021), ECF No. 35-1.) That filing highlights the Second Circuit’s decision in *In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005), and argues that the ATSSSA, which the Second Circuit determined was a complete preemption statute, “is structurally similar to the PREP Act.” (Dkt. 18-1, at 5; *see also id.* at 9–10.) The Court, however, disagrees with the government’s position in *Bolton* and its comparison of the PREP Act to the ATSSSA. True, similar to the PREP Act, the ATSSSA created an administrative “Victim Compensation Fund” to provide relief for injuries resulting from the September 11, 2001 aircraft hijackings and crashes. *In re WTC Disaster Site*, 414 F.3d at 373–74 (quoting ATSSSA, § 405(c)). But, crucially, the ATSSSA *also created* an alternative, *exclusive* federal cause of action for claims “arising out” of the plane hijackings and crashes:

There shall exist a Federal cause of action for damages arising out of the hijacking and subsequent crashes of American Airlines flights 11 and 77, and United Airlines flights 93 and 175, on September 11, 2001 [T]his cause of action shall be the *exclusive* remedy for damages arising out of the hijacking and subsequent crashes of such flights.

Id. at 374 (emphasis added) (quoting ATSSSA § 408(b)(1)). Using the term “ATSSSA-created cause of action” or “ATSSSA-created federal cause of action” no fewer than five times in its discussion of complete preemption, the Second Circuit concluded that it was this exclusive federal remedy, which could be brought only in the United States District Court for the Southern District of New York, that gave the statute its extraordinary preemptive force, such that any claim within its scope was really a federal-law claim. ... The PREP Act creates no similar exclusive federal cause or right of action. As already discussed, the PREP Act is an immunity statute that simply limits the causes of actions for claims falling within its ambit, leaving only claims involving “willful misconduct” as able to be adjudicated in federal court, after administrative remedies have been exhausted. *See* 42 U.S.C. §§ 247d-6d(a)(1), 247d-6d(d)(1), 247d-6d(e)(1); *see also* 42 U.S.C. § 247d-6e(d)(1).

As such, the law is clear that the PREP Act does not completely preempt state-law claims such that those claims are really federal-law claims, and Defendants’ motion should be denied

accordingly.

IV. THE EMERGENCY OR DISASTER TREATMENT PROTECTION ACT (EDTPA) WAS REPEALED IN ITS ENTIRETY ON APRIL 6, 2021 AND FAILS TO AFFORD IMMUNITY TO DEFENDANTS HEREIN AGAINST THE INSTANT CLAIMS.

From the outset, should the Court find that the PREP Act does not apply, and accordingly that this Court has no subject matter jurisdiction over the instant matter, this Court need go no further in the analysis of the applicability of the EDTPA as the matter should be remanded to state court for determination of this issue, if necessary.

Notwithstanding the same, on April 6, 2021, Governor Cuomo duly signed into law Assembly Bill A03397 entitled “An act to repeal Article 30-d of the Public Health Law relating to the Emergency or Disaster Treatment Protection Act” (codified as Public Health Law Article 30-D). In no uncertain terms, the law “repeals the emergency disaster treatment protection act which protects health care facilities and health care professionals from liability that may result from treatment of individuals with COVID-19 under conditions resulting from circumstances associated with the public health emergency.”

Notably, the repeal of the EDTPA did not create any new causes of action, but rather removed the limited liability shield for health care facilities related to injuries alleged to have been caused by the acts or omissions of said health care facilities and professionals in the early days of the COVID emergency. In effect, the law merely removes a dispositive affirmative defense from potentially culpable health care facilities and therefore requires them to duly defend longstanding available causes of action brought against them. Furthermore, as set forth in greater detail below, the passage of A03397 patently applies retroactively to March 7, 2020, and encompasses the claims of the case at bar. (See Affidavit of the Bill Sponsor, Assemblyman Kim, Leitner Decl., Ex. E). As such, Defendant’s motion has no basis and should be denied accordingly.

(A) The Sponsor’s Legislative Intent is of Paramount Consideration.

It is well settled that in order “to determine whether a statute should be applied retroactively, courts must look at the legislative history to see if it “reveals that the purpose of new legislation is to clarify what the law was always meant to say and do.” *Majewski v. Broadalbin–Perth Cent. Sch. Dist.*, 91 N.Y.2d 577, 583, 673 N.Y.S.2d 966, 696 N.E.2d 978 (1998); *Matter of OnBank & Tr. Co.*, 90 NY2d 725, 730-31 (1997). The manner in which legislative intent is determined has also been well settled by the Courts. “There are several key legislative documents which shed light on the statute's purpose. The memoranda submitted by the Amendment's sponsors in the Senate and Assembly are helpful in that regard. In New York, while not determinative, a legislator's sponsor memo submitted contemporaneously with the legislation “is entitled to considerable weight in discerning legislative intent.” *Vatore v. Comm'r of Consumer Affairs*, 83 N.Y.2d 645, 651, 612 N.Y.S.2d 357, 634 N.E.2d 958 (1994) (quoting *Matter of Knight–Ridder Broad. v. Greenberg*, 70 N.Y.2d 151, 158, 518 N.Y.S.2d 595, 511 N.E.2d 1116 (1987)). The Court of Appeals held that “simply put, there must be a “clear” expression of legislative intent to apply a statute retroactively” which is patently evident in the case at bar. *Id.*, 673 N.Y.S.2d 966, 696 N.E.2d 978.

The plainly stated intent of the Bill’s sponsor, Assemblyman Kim, unequivocally established that the removal of immunity and liability protection for health care facilities was to be applied **retroactively** in an effort to restore the rights of claimants. This legislative intent was broadly set forth by Mr. Kim within the sponsor’s Memorandum, which states the following, with emphasis added:

As the COVID-19 pandemic has progressed in New York State, **it is now apparent that negligence by administrators and executives of nursing homes has occurred at an extraordinary degree.** The consequences have been tragic: as of early May 2020,

nearly five thousand of New York's elderly and most vulnerable residents have succumbed to this disease, and **to date, there has been zero accountability nor transparency for these preventable deaths.** The ELFA bill (A.9506/S.7506) in the FY 2021 state budget bills codified Article 30-D of the Public Health Law. In particular, Article 30-D egregiously uses severe liability standards as a means to insulate health care facilities and specifically, administrators and executives of such facilities, from any civil or criminal liability for negligence. **Repealing this article is a much-needed step to holding health care administrators accountable** and doing everything possible to stop even more preventable deaths from happening.

To further clarify the legislature's unmistakable intent that the subject Bill should have retroactive effect, the issue was duly and publicly pronounced on March 4, 2021 during open debate on the Assembly floor, prior to the Assembly vote, at which time Assemblyman Kim was questioned about this very issue in his capacity as the Sponsor, and offered the following responses (See Affidavit of Assemblyman Kim, Leitner Decl., Ex. E).

MS. BYRNES: **What is your intent, though?**

MR. KIM: **My intent is** because they did not -- because the Executive took away the patients' and the residents' rights to get access to information and were banned from entering the premise [sic] to prove if there was any gross negligence, if there was any reckless behavior. And the Executive also issued a mandate saying that medical records are waived. So he -- he made it impossible to prove -- for the families to prove if there were any reckless intentional behavior. So as we strike this, **I do believe that it should be applied retroactively...**" (see p. 49)

To clarify further still and so as to avoid any confusion, Assemblyman Kim reiterates and maintains his position that the subject bill was always intended to have retroactive effect to include all claims properly alleged during the period of the COVID-19 pandemic as established by his sworn Affidavit attached hereto and made a part hereof. See Affidavit of Assemblyman Kim, Leitner Decl., Ex. E). In pertinent part, Mr. Kim sets forth that:

5. As set forth by the Assembly Memorandum, the purpose of the Bill is **twofold: 1) to hold health care facilities, administrators, and executives accountable for failures which led to the deaths of thousands of nursing homes residents**, including inadequate preparation, failure to follow protocols, and inadequate care relating to COVID-19 during the COVID-19 emergency period, **and 2) to stop even more preventable deaths from occurring in the future.**

6. **As the Sponsor of the Bill, I want to make it clear that the Bill was intended to retroactively repeal the unfair immunity law** so as to afford victims of nursing home negligence their day in Court should they so choose, and seek justice pursuant to the available causes of action under state law which provide civil remedies to protect nursing home residents. **To be certain, the intent of the law is to repeal the Emergency or Disaster Treatment Protection Act, Public Health Law Article 30-D, retroactively as of March 7, 2020.**

7. **The retroactive intent of the subject Bill was made known to the entire voting body during the Assembly Floor Debate on March 4, 2021, prior to the Assembly vote. During the Assembly Floor Debate, as the Sponsor of the Bill, I was questioned as to whether the Bill was intended to retroactively repeal the immunity law, and I testified unequivocally that it should be applied retroactively.** A copy of the relevant Assembly testimony is attached to this Affidavit as Exhibit “B”.

8. After the Floor Debate, the Bill passed through the Assembly by a vote of 149 to 1, and on April 6, 2021, NYS Governor Cuomo signed this legislation into law which fully repeals the State’s COVID-19 immunity statute, the Emergency or Disaster Treatment Protection Act (EDTPA) under Article 30-D of the Public Health Law.

(See Affidavit of Assemblyman Kim, Leitner Decl., Ex. E, at Ex. B therein).

In no uncertain terms, the Bill’s sponsor has made it abundantly clear that A03397 was always “intended to retroactively repeal the unfair immunity law” so as to “hold health care facilities, administrators, and executives accountable for failures which led to the deaths of thousands of nursing homes residents ...during the COVID-19 emergency period.” He goes on to clarify that this was “made known to the entire voting body during the Assembly Floor Debate on

March 4, 2021,” prior to the vote held on and therefore represents the stated, openly held legislative intent of the Bill’s sponsor.

The Second Circuit Court of Appeals recently addressed a similar issue regarding the retroactive applicability of a law based upon the legislative intent holding that “[b]ased on the absence of language barring the application” of the law’s retroactive effect, “we cannot infer that the Legislature intended the Amendment to apply only prospectively.” *CFCU Community Credit Union v. Hayward*, 552 F.3d 253 (2009). In *CFCU*, the Court considered whether a 2005 amendment to the homestead exception, which was technically silent on the issue of retroactive application, would have retroactive effect based upon the legislative intent. The Court underscored the well settled approach that the duly stated intention of the bill’s sponsor must dictate the interpretation of legislative intent. Of great importance, Courts have held that “statements and opinions of legislators uttered in the debates are not competent aids to the court in ascertaining the meaning of statutes.” *Majewski v. Broadalbin–Perth Cent. Sch. Dist.*, 91 N.Y.2d 577, 583, 673 N.Y.S.2d 966, 696 N.E.2d 978 (1998) (quoting *Woollcott v. Shubert*, 217 N.Y. 212, 221, 111 N.E. 829 [1916]).¹² Instead, the intention of the bill’s sponsor, in this case Mr. Ron Kim, is directive.

The specific language of intent in the Bill Memorandum leaves no uncertainty as to the purpose:

“Repealing this article is a much-needed step to holding health care administrators accountable **and** doing everything possible to stop even more preventable deaths from happening.”

¹² To that end, the United States Supreme Court has noted, “it is impossible to determine with certainty what construction was put upon an act by the members of a legislative body that passed it by resorting to the speeches of individual members thereof. Those who did not speak may not have agreed with those who did; and those who spoke might differ from each other.” *United States v. Freight Assn.*, 166 U.S. 290, 318, 17 S.Ct. 540 (1897). Accordingly, the comments of non-sponsoring members of the legislature do not guide interpretation as Courts solely rely upon the stated intent of the bill’s sponsor. In case at bar, the Bill’s sponsor, Mr. Ron Kim, unmistakably established his intent that the bill was to have retroactive effect, as set forth in the memorandum, on the floor of the New York State Assembly, and further clarified by his attached Affidavit (See Affidavit of Assemblyman Kim, Leitner Decl., Ex. E). As such, commentary, statements, and opinions of other legislators are not relevant to the determination of legislative intent for the purposes of this analysis.

As set forth by Assemblyman Kim, the purpose of the Bill is twofold:

- 1) to hold health care facilities, administrators, and executives accountable for failures which led to the deaths of thousands of nursing homes residents, including inadequate preparation, failure to follow protocols, and inadequate care relating to COVID-19 during the COVID-19 emergency period, **and**
- 2) to stop even more preventable deaths from occurring in the future.

As such, the explicit purpose of the law is to afford victims of nursing home negligence their day in Court to hold health care facilities, administrators, and executives accountable for the failures which led to the deaths of thousands of nursing homes residents. To be sure, the subject deaths have already happened, and as such, “[t]he remedial purpose of the amendment would be undermined if it were applied only prospectively”. *Matter of OnBank & Trust Co.*, 90 N.Y.2d, at 731, 665 N.Y.S.2d 389, 688 N.E.2d 245; see also *Bros. v Florence*, 95 NY2d 290, 298-300 [2000].

Further to this, the text of the subject repeal of the EDTPL directs that it is to “take effect immediately”. In determining legislative intent regarding whether retroactivity applies, courts have often found that language to “take effect immediately” to be a persuasive indicator of the intent for retroactivity. “While this language is not alone determinative, it does “ ‘evinced [] a sense of urgency’ ”. *Bros. v Florence*, 95 NY2d 290, 298-300 [2000] citing *Majewski v. Broadalbin-Perth Cent. Sch. Dist.*, 91 N.Y.2d 577, 584, 673 N.Y.S.2d 966, 696 N.E.2d 978 (1998); see also *Becker v. Huss Co.*, 43 N.Y.2d 527, 541, 402 N.Y.S.2d 980 (1978)(“Yet, from the direction that it be effective immediately, it must be inferred that the Legislature was interested in affecting as many cases as practicable”).

(B) Due Process & Public Policy Warrant Retroactive Application of A03397.

It is well settled that “remedial legislation should be given retroactive effect in order to effectuate its beneficial purpose.” *Matter of Gleason*, 96 N.Y.2d 117, 122, 726 N.Y.S.2d 45, 749

N.E.2d 724 (2001) (citing *Majewski v. Broadalbin-Perth Cent. Sch. Dist.*, 91 N.Y.2d 577, 584, 673 N.Y.S.2d 966, 696 N.E.2d 978 (1998)). “Remedial statutes are those designed to correct imperfections in the prior law.” N.Y. Stat. § 54(a), Comment (McKinney 2019). The gravamen of the subject bill is the quintessential remedial measure inasmuch as it does not create a new cause of action, nor does it impose any new liability that did not previously exist. In this regard, the availability of causes of action pursuant to Public Health Law § 2801-d, which provides a private statutory cause of action for residents of nursing homes injured because of the nursing home’s deprivation of certain “resident’s rights,” and under state law theories of negligence, have existed for decades to protect elderly nursing home residents. Instead, the repeal of the EDTPA merely remedies and “corrects imperfections” to the prior law (i.e. the EDPTA) based upon the intention of the legislature and governor, by removing the limited liability shield.

Furthermore, the retroactive effect of A03397 preserves the due process rights of all parties in every respect. Both the federal and New York State constitutions provide that “[n]o person shall ... be deprived of life, liberty or property, without due process of law.” U.S. Const. amend. V; N.Y. Const. Art. I, § 6 (McKinney, Westlaw through L. 2019, chapter 579). “Procedural due process imposes constraints on governmental decisions which deprive individuals of ‘liberty’ or ‘property’ interests,” *Mathews v. Eldridge*, 424 U.S. 319, 332, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976), by requiring the Government to provide some sort of procedural protections when a deprivation occurs, see *Zinerman v. Burch*, 494 U.S. 113, 125-27, 110 S.Ct. 975, 108 L.Ed.2d 100 (1990). However, as the Supreme Court has recognized, “the State remains free to create substantive defenses or immunities for use in adjudication,” and that doing so does not violate the potential claimant’s due process rights when it does so. *Seidemann v. Professional Staff Congress Local 2334*, 432 F.Supp.3d 367 (S.D.N.Y. 2020) quoting *Logan v. Zimmerman Brush Co.*, 455 U.S. 422,

432, 102 S.Ct. 1148, 71 L.Ed.2d 265 (1982); accord *Stoianoff v. Commissioner of Motor Vehicles*, 107 F. Supp. 2d 439, 448 (S.D.N.Y. 2000). This holding unequivocally establishes that the repeal of such an act would also create no imposition upon the constitutional right to due process as against any party. To that end, Mr. Kim addressed this notion during the floor debate of the subject bill in furtherance of his legislative intent:

“according to the U.S. Constitution and the New York State Constitution which prohibit ex post facto criminal liability, this means it is not lawful to retroactively create a crime. But no similar restrictions apply to civil liability.” (See Affidavit of Assemblyman Kim, Leitner Decl., Ex. E, at Ex. B therein, p. 48).

The Bill’s sponsor, Assemblyman Kim, patently clarified in the presence of the entire voting body that the EDTPA could rightfully be repealed without violation of any individual rights pursuant to the state and federal constitutions by acknowledging that, while perhaps some retroactive limitations might exist in finding criminal liability, “no similar restriction appl[ies] to civil liability.” As this Court is aware, the repeal of the EDTPA refers to civil liability and ultimately removes the liability shield of health care facilities in defense of claims brought by aggrieved parties.

It should also be noted that, in alignment with the case law set forth above, the immunity established by the EDTPA was *enacted* retroactively without threat of any due process violation, and in like manner, may be *repealed* retroactively without any such consideration.

To that end, it must also be underscored that the repeal of the EDTPA does not create a new cause of action for any aggrieved party, but rather, it merely removes the immunity and liability shield that was made available to health care facilities in defense of any such claims. Accordingly, as was Mr. Kim’s intention, the repeal of the civil liability shield simply restores the rights of all parties to prosecute and defend claims in a manner consistent with existing law:

“The bill would return to the status quo and eliminate the legal immunity from liability enacted one year ago for negligence resulting from treatment of individuals during the COVID-19 pandemic period. The bill repeals Article 30-d of the Public Health Law, the Emergency or Disaster Treatment Protection Act. The law affords healthcare facilities, including nursing home and long-term facilities and certain professionals and corporate executives immunity from liability, civil or criminal, for harm or damages alleged to have been sustained as a result of an act or omission in the course of providing healthcare services during the COVID-19 emergency period.” (See Affidavit of Assemblyman Kim, Leitner Decl., Ex. E, at Ex. B therein, p. 42-43).

V. THE EDTPA DOES NOT APPLY TO PLAINTIFF’S CLAIMS HEREIN.

A. Defendants’ Negligence and Violations Occurred Prior to the Pandemic.

Even assuming the immunity law was still in effect, Plaintiff has alleged that significant negligent acts and omissions by the Defendant nursing home **occurred prior to the pandemic and prior to the enactment of immunity under the EDTPA**. Specifically, the Complaint in this matter explicitly alleges the following:

2. In 2019, prior to the current coronavirus outbreak, Our Lady of Consolation was cited by government inspectors and regulators multiple times for violations of federal and state regulations for failing to provide and implement proper infection and control procedures, and failing to implement contact isolation precautions for residents known or suspected to have serious illness easily transmitted.

3. In addition, prior to the coronavirus emergency in New York, on February 6, 2020, Our Lady of Consolation was placed on notice by Centers for Medicare & Medicaid Services that coronavirus infections can rapidly appear and spread, and that it was critical that the nursing home be prepared by planning for infectious disease response, including having sufficient personal protective equipment (PPE) available.

4. However, Our Lady of Consolation failed to take proper precautions to help prevent the development of infections prior to and leading up to the COVID-19 pandemic. As a direct and foreseeable consequence of the Defendants’ failures, as of June 2, 2020, there was a confirmed COVID-related death count of 39 residents who died

inside Our Lady of Consolation due to COVID-19, as well as an unknown, but potentially greater, number of Our Lady of Consolation COVID-19 resident deaths outside of the facility. According to the New York State Department of Health, Our Lady of Consolation claims the highest COVID-related death count of any nursing facility in Suffolk County, and the sixth highest death count in the State of New York.

47. Our Lady of Consolation was issued 31 citations during Certification and Complaint Surveys for violations of public health code between 2016 and 2020, more than the average nursing home, according the New York State Department of Health (“DOH”) data.

48. On or about September 12, 2019, Our Lady of Consolation was cited by the New York State Department of Health (“DOH”) for federal violations, and violations of its own written policies and procedures, for failing to order Contact Isolation Precautions for a resident

53. In or about January 2020, and likely earlier, Defendants were made aware of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spreading world-wide and nationally, known colloquially as the coronavirus, that caused severe medical distress and death in individuals who contracted the disease, especially the elderly.

(See Plaintiff’s Amended Complaint, Leitner Decl., Ex. A). To be sure, Plaintiff’s causes of action for negligence and violation of the Public Health Law pertain to acts and omissions that took place prior to the enactment of the EDTPA which are not subject to any immunity or liability shield. In the case at bar, Plaintiff has alleged that Defendant failed to implement a preparatory infection control plan as directed by the Centers for Medicare & Medicaid Services as well as by state and federal regulation as follows:

10 NYCRR 415.19 Infection control. The facility shall establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection.

42 CFR 483.80 Infection control. The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help

prevent the development and transmission of communicable diseases and infections.

Defendant's violation of New York State regulation 10 NYCRR 415.9 and Federal regulation 42 CFR 483.80 sound in its negligent failure to have an "infection prevention and control" program in place *prior* to the COVID-19 crisis as required by law. Insomuch as Plaintiff's complaint include allegations related to a period prior to the enactment of the EDTPA, dismissal of the instant case would be patently inappropriate thereby warranting denial of Defendant's motion.

B. Defendants' Actions are Outside the Confines of the EDTPA.

In addition, the explicit terms of the law dictate that the immunity provision only applies in special limited circumstances where the alleged act or omission occurs when Defendants are 1) providing services pursuant to a COVID-19 emergency rule; 2) the treatment of Ms. Martinez is impacted by the health care facility's decisions or activities in response to the COVID-19 outbreak and in support of the state's directives; **and** 3) Defendants are providing services in good faith. N.Y. Pub. Health Law § 3082(1). Defendants offer no admissible proof, or any proof, of the applicability of or compliance with any of these statutory requirements. The sole basis for the motion is defense counsel's conclusory statement, which avers no personal knowledge, and which is inadmissible and insufficient. See, *Warrington v. Ryder Truck Rental, Inc.*, 826 N.Y.S.2d 152, 153 (2nd Dept. 2006) ("An attorney's affirmation that is not based upon personal knowledge is of no probative or evidentiary significance"); *JMD Holding Corp. v. Cong. Fin. Corp.*, 828 N.E.2d 604, 612 (2005) ("A conclusory affidavit or an affidavit by an individual without personal knowledge of the facts does not establish the proponent's prima facie burden"). Defendants utterly failed to meet their burden of proof and the motion should be denied outright.

In fact, Plaintiff's claims are the opposite, to wit: Defendants were not providing services

to Plaintiff pursuant to a COVID-19 emergency rule, but instead were providing care prior to the COVID-19 rule pursuant to a contract with Plaintiff; Defendants were not providing care in accordance with State directives as required under the law – in fact, Defendants failed to provide care pursuant to directives; and Defendants failed to provide care in good faith, which is confirmed by Defendants’ extensive infection control violations pre-dating COVID-19, and Defendants’ affirmative admissions as to various infection control violations during the pandemic, as detailed *infra*.

While New York courts have yet to rule on this issue, the United States District Court, Northern District of Illinois last week issued a decision in an analogous nursing home negligence case involving allegations of failure to implement proper infection control protocols to prevent the spread of COVID-19. In finding that the nearly identical state civil immunity law enacted to cover health care providers rendering medical treatment in support of the COVID-19 outbreak did not apply because the nursing home must be “providing health care services in response to the COVID-19 outbreak”, the Court explained:

There’s a difference between allowing the virus to spread by taking no preventative measures, and spreading the virus while affirmatively treating it or trying to prevent spread. Only the latter is immunized, and it’s not clear from the complaints that the staff infected the residents in the course of providing COVID-related treatment—it’s just as reasonable of an inference that transmission occurred during routine, non-COVID-related care.

See *Brady v. SSC Westchester Operating Company LLC*, No. 2-cv-4500 (N.D. Ill. 2021), Leitner Decl., Ex. F). Analogously herein, for any immunity to apply, Defendants bear the burden of proving they were “providing services pursuant to a COVID-19 emergency rule”. However, Defendants offer no proof whatsoever that they were providing services pursuant to the emergency rule, and Plaintiff alleges the precise opposite – that Defendants failed to take preventive measures

and failed to act pursuant to emergency directive.

VI. PLAINTIFF PROPERLY ALLEGES CAUSES OF ACTION FOR GROSS NEGLIGENCE AND RECKLESS CONDUCT, AND THE REPEALED IMMUNITY PROVISION EXPLICITLY PERMITS SUCH CLAIMS.

To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must plead facts that, if accepted as true, “state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). A complaint is facially plausible when the “plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). For motions under Rule 12(b)(6), the court assumes the truth of all facts asserted in the operative complaint and draws all reasonable inferences from those facts in favor of the non-moving plaintiff. *Global Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 154 (2d Cir. 2006).

In addition to the specific allegations of in Plaintiff's Amended Verified Complaint as to Defendants' longstanding failures and admissions of infection control and prevention violations detailed *infra*, Plaintiff's Complaint sets forth the following allegations in the Fourth Cause of Action for Gross Negligence:

- Defendants acted in so careless a manner as to show complete disregard for the rights and safety of others;
- Defendants acted or failed to act knowing that their conduct would likely result in injury or damage;
- Defendants acted in so reckless a manner or failed to act in circumstances where an act was clearly required, so as to indicate disregard of the consequences of their actions or inactions;
- Defendants conduct, as outlined above, was willful;
- Defendants conduct, as outlined above, was in reckless disregard.

(Leitner Decl., Ex. A, ¶136-151). As clearly established by the well settled case law, the Court should give the Plaintiff herein the benefit of every favorable inference and accept the allegations

contained in the Complaint as true at this juncture.

It should also be noted that Defendants neglect to include an affirmation from any type of medical expert in support of its claim that any of Plaintiff's claims should be dismissed. At best, Defendants' motion is nothing more than the conclusory opinions of Defendants' attorney that the negligence alleged in this action is merely "ordinary". In short, the allegations of recklessness and gross negligence by Defendants are as clearly stated as they are viable. When "accepted as true" and the Plaintiff is "afforded the benefit of every favorable inference," there is no basis in procedure or law to support Defendants' application and the motion should be denied in its entirety.

Of great importance, the Plaintiff's claim for gross negligence/reckless conduct as against the moving Defendants is statutory and not based in common law. Public Health Law §2801-d(2) expressly provides that: "where the deprivation of any such right or benefit is found to have been willful or in reckless disregard of the lawful rights of the patient, punitive damages may be assessed." The statute reflects a public policy to use punitive damages as a tool to address the reckless violation of rights of nursing home residents where compensatory damages may be an inadequate deterrent for the defendant. In this regard, New York Courts have readily awarded punitive damages in PHL 2801-d cases in analogous circumstances, or otherwise confirmed the availability and less stringent standard for proving same, many of which the nursing home's conduct was less egregious than the care provided by Defendants herein.¹³

¹³ See, e.g. *Hairston v Liberty Behavioral Mgt. Corp.*, 2016 NY Slip Op 02724 (138 AD3d 467)(1st Dept. 2016); *Allicino v. Ozone Acquisition, LLC*, Index No. 600130/16 (Sup.Ct. Nassau Co. March 12, 2019); *Osborne v Rivington House*, 2008 NY Slip Op 50975(U) [19 Misc 3d 1132(A) (Sup.Ct. NY Co.)]; *Demicoli v Townhouse Operating Co., LLC*, 2009 NY Slip Op 33287(U)(Sup.Ct.Nassau.Co. Index No. 1549/07); *Mueller v Elderwood Health Care at Oakwood*, 2011 NY Slip Op 50555(U) (Sup.Ct.Erie.Co Index No. 2008-1416)(April 11, 2011); *Dunn v Schervier Nursing Care Center*, No. 147342005, 2013 WL 6702677 (N.Y. Sup. Ct. Bx. Co. June 04, 2013); *Vaynberg v Saint Vincents Catholic Medical Centers of New York*, No. 37727/06, 2009 WL 3412982 (N.Y. Sup. Ct. Oct. 14, 2009); *Austin v the Jewish Home*, No. 3041962010, 2015 WL 1850183 (N.Y. Sup. Ct. Mar. 20, 2015); *Coleman v. Eden Park Nursing Homes*, No. 0019362/0051, 2007 WL 2236563 (N.Y. Sup. Ct. Albany Co. Apr. 04, 2007); *Meltzer v Pine Grove Manor, II LLC*, No. 3362/2009, 2016 WL 510391, at (N.Y. Sup.Ct.QueensCo. Feb. 02, 2016), *See also*, *Turner v Northern Manhattan Nursing Home, Inc.*, No. 161278/15, 2018 WL 1257003,(N.Y.Sup.Ct. Mar. 12, 2018).

In addition, no discovery has been conducted as of yet in this matter. At this early stage of the litigation, Defendants have not filed an Answer, and there has been no exchange of any documentation or depositions having been conducted to date. To be sure, questions of fact cannot even be addressed, much less resolved, without the completion Defendants' depositions and document production.¹⁴

CONCLUSION

WHEREFORE, for the foregoing reasons, Plaintiff respectfully requests that Defendants' motion be denied in its entirety.

Dated: Melville, New York
April 16, 2021

LEITNER VARUGHESE WARYWODA PLLC
Attorneys for Plaintiff

/s/ Brett R. Leitner

By: Brett R. Leitner, Esq.
Justin Varughese, Esq.
Nicholas E. Warywoda, Esq.

425 Broadhollow Road, Suite 417
Melville, New York 11747
(212) 671-1110

¹⁴ In this regard, courts have long held that it is premature to dismiss any claims at this stage of the case. *Gardner v. Cason, Inc.*, 82 A.D.3d 930, 918 N.Y.S.2d 769 (2d Dept 2011). "This is especially so where the opposing party has not had reasonably opportunity for disclosure prior to the making of the motion." *Id.* at 931, see also *Baron v. Incorporated Village of Freeport*, 143 A.D.2d 792, 533 N.Y.S.2d 143 (2d Dept 1988). In such a circumstance, at a minimum, the Court should deny Defendants' motion with leave to renew after the completion of discovery. *Id.* at 932, see also *Gruenfeld v. City of New Rochelle*, 72 A.D.3d 1025, 900 N.Y.S.2d 144 (2d Dept. 2010); *Aurora Loan Services, LLC v. LaMattina & Associates, Inc.*, 59 A.D.3d 578, 872 N.Y.S.2d 724 (2d Dept. 2009); *Martinez v. Ashley Apts., Co., LLC*, 44 A.D.3d 830, 842 N.Y.S.2d 918 (2d Dept. 2007); *Thyme v. City of New York*, 22 A.D.3d 571, 801 N.Y.S.2d 744 (2d Dept. 2005); see generally CPLR 3212(f).